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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,067	12/23/1999	A-Li W. Hu	0942.4340002	8277

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/472,067

Applicant(s)

HU ET AL.

Examiner

Jane Zara

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54, 76 and 77 is/are allowed.
- 6) ☒ Claim(s) 35-53 and 55-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9-14-00</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 1-16-04.

Claims 35-77 are pending in the instant application.

Information Disclosure Statement

The Japanese patent, JP 63-113359, submitted as reference AL1 in the IDS filed 9-14-00, has not been considered because no translation has been provided for this document.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 35-41, 43-53 and 55-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the Office action mailed 7-16-03.

Applicant's arguments filed 1-16-04 have been fully considered but they are not persuasive. Applicants argue that the instant specification discloses a method of synthesizing repeat containing sequences having restriction sites created by the junction of adjacent copies of repeat containing sequences. Applicants argue that the

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examples provided on pages 11-13 and 17-19 set forth exemplary restriction sites for the instant invention. Contrary to Applicants' assertions, the method provided and the examples furnishing exemplary restriction sites encompassed by the instant invention, while providing for a method of generating nucleic acid ladders useful in molecular biology, do not provide adequate representation of the broad array of compounds encompassed by the claims. The claims read on a myriad of sequences whose general theme is one of tandem repeat containing sequences that, upon restriction digestion, yield nucleotide sequences of incremental sizes that are useful for molecular size markers for nucleic acid sizing. Adequate representation of this expansive genus - comprising any double stranded nucleic acid molecule with two or more copies of a repeat containing sequence, wherein the top strand has substantially the same percentage of each respective nucleotide as in the bottom strand, and wherein a restriction site is created by the junction of adjacent copies of said repeat containing sequence - has not been provided in the instant disclosure.

New Rejections and Rejections Necessitated by Amendments

Applicant's arguments with respect to claims 35, 36, 39, 41, 43, 48, 49 and 51 under 102(b) have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in line 7, claim 42, what "complements thereof" pertains to (e.g. is it a nucleic acid molecule with two copies of SEQ ID NO: 1, the first copy as written, the second copy as the complement, and any combination of these two, in any orientation?) Appropriate clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 36, 38-43, 46, 47, 50-53, 55, 63, 64, 73, 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Okazaki et al.

Okazaki et al (Neurobiology of Aging, Vol. 16(6): 883-894, 1995) teach a host cell, vector, plasmid or nucleic acid molecule comprising two or more copies of a repeat containing sequence (i.e. of SEQ ID Nos: 3 or 4), which sequence is from 5 to 100 pairs, and the top strand of repeat containing sequence has substantially the same percentage of each nucleotide as in bottom strand, and which repeat containing sequence comprises a palindromic sequence, a restriction site generating blunt ends (Eco RV) is created by the junction of adjacent copies of the repeat containing

sequence, nucleic acid molecule is a DNA or DNA/RNA hybrid, is in circular or linear form or a vector comprising an origin of replication and 2 fragments are produced upon digestion with the restriction endonuclease (see the sequence alignments attached to the Okazaki reference e.g. SEQ ID NO: 3 and 4 of the instant claims and Accession No. S82024; see also right hand column of page 884; right hand column of page 885; figure 1 on page 886; figure 3 on page 887).

Allowable Subject Matter

Claims 54, 76 and 77 appear free of the prior of record.

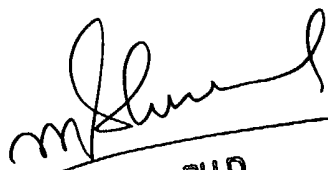
Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ
4-11-04